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10/800,291	03/12/2004	Zoltan G. Toth	14669.0064USU1	8286

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Merchant & Gould  
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EXAMINER
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SCHLENTZ, NATHAN W

ART UNIT	PAPER NUMBER
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1616

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12/05/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/800,291	<b>Applicant(s)</b> TOTH ET AL.	
	<b>Examiner</b> Nathan W. Schlientz	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 14, 27 and 60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-13, 15-26 and 28-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/4/08, 10/1/08, 10/2/08</u> .                                | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

Claim 31 was amended and claim 61 was newly added in an amendment filed 29 September 2008. As a result, claims 1-61 are pending, but claims 14, 27 and 60 have been withdrawn in an Amendment filed 21 February 2007. As a result, Claims 1-13, 15-26, 28-59 and 61 are examined herein on the merits for patentability. No claim is allowed at this time.

### ***Information Disclosure Statement***

The information disclosure statement filed 02 October 2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. It is noted by the examiner that a copy of WO 02/42290 was supplied by Applicants, but was not listed on an IDS under Foreign Patent Documents. Applicants listed WO 2004/042290 on the IDS but did not supply a copy.

The information disclosure statements (IDS) submitted on 04 August 2008 and 01 October 2008 were filed after the mailing date of the non-final action on 27 March 2008. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Withdrawn Rejections***

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-13, 15-26, 28-59 and 61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 21-24 of copending Application No. 11/283,276 (Toth ‘276).

More specifically, claims 1-13, 15-26 and 28-59 of the instant application are directed to a stable mixture of crystalline polymorph Form I and Form II of desloratadine and a pharmaceutical formulation comprising said stable mixture and a pharmaceutically acceptable excipient, wherein said stable mixture comprises: from about 20 wt.% to about 80 wt.% desloratadine Form I; from about 80 wt.% to about 20 wt.% desloratadine Form II; and said stable mixture is made by a process involving one or more organic solvents selected from the group consisting of: n-heptane; toluene; isopropanol; and mixtures thereof. Claims 14, 27 and 60 of the instant application are directed to a method of treating allergenic reactions in a mammal comprising administering said pharmaceutical formulation to said mammal.

Claims 21-24 of Toth '276 are directed to a mixture of crystalline polymorph Form I and Form II of desloratadine and a pharmaceutical formulation comprising said mixture, wherein said mixture comprises: from about 35 wt.% to about 82 wt.% desloratadine Form I; from about 65 wt.% to about 18 wt.% desloratadine Form II; and from about 50 ppm to about 4000 ppm of one or more organic solvents selected from the group consisting of: n-hexane; n-heptane; toluene; ethyl acetate; isobutyl acetate; butanol; isobutanol; chloroform; and mixtures thereof. Claim 25 of Toth '276 is directed to a method of treating allergenic reactions in a mammal comprising administering said pharmaceutical formulation to said mammal.

However, while Toth '276 does not claim the physicochemical properties (i.e., melting temperature, stability, flowability, solubility, dissolution rate, and bioavailability) of said stable mixture, as claimed in claims 4-13, 17-26 and 31-36 of the instant

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application, it is well within the purview of the skilled artisan to measure the physicochemical properties of said stable mixture by measuring, for example, the melting temperature and resistance to polymorphic transformation, chemical degradation and decomposition that said stable mixture possesses. One of ordinary skill in the art at the time the instant application was filed would have been motivated to conduct routine experimentation in order to determine whether the physicochemical properties (i.e., melting temperature, stability, flowability, solubility, dissolution rate, and bioavailability) of said stable mixture, to be incorporated into a pharmaceutical formulation, are constant and thus exhibit batch-to-batch consistency and uniformity from a drug manufacturing and quality assurance perspective.

As a result, although claims 1-13, 15-26 and 28-59 of the instant application are not identical to claims 21-24 of Toth '276, the aforementioned claims are not patentably distinct each from the other because said claims are substantially overlapping in scope, with respect to said organic solvents and said weight percent ranges and ratios of crystalline polymorph Form I and Form II of desloratadine, as discussed hereinabove.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It should be mentioned however that while claims 14, 27 and 60 of the instant application are currently withdrawn from further consideration as being directed to a non-elected invention. In the event that the elected product claims are found allowable, the requirement for restriction between the elected product claims and the non-elected method of using claims will be withdrawn, and the rejoined method of using claims will

be fully examined for patentability in accordance with 37 CFR 1.104 and *In re Ochiai*, 71 F.3d 1565, 37 USPQ2d 1127 fled. Cir. 1995). In the event of rejoinder, Applicants are advised that claims 14, 27 and 60 of the instant application would be provisionally rejected under the judicially created doctrine of non-statutory obviousness-type double patenting as being unpatentable over conflicting claim 25 of Toth '276. This would be a provisional non-statutory double patenting rejection since conflicting claim 25 of Toth '276 have not yet in fact been patented and are substantially overlapping in scope (i.e., drawn to a method of treating allergenic reactions in a mammal comprising administering said pharmaceutical formulation to said mammal) to claims 14, 27 and 60 of the instant application.

### ***Response to Arguments***

Applicant's arguments filed 29 September 2008 have been fully considered but they are not persuasive. Applicants argue on page 15 that Toth '276 requires about 50 ppm to about 4000 ppm of any one of isobutyl acetate, n-heptane, n-hexane, ethyl acetate, butanol, isobutanol, toluene, chloroform and combinations thereof, which is in contrast to the instant claims which do not require these solvents. However, the instant claims are drawn to compositions or methods with the transitional phrase "comprising". The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See MPEP 2111.03. Therefore, the instant claims do not exclude the solvents as claimed by Toth '276.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1-13, 15-26, 28-59 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Villani et al. (US 4,659,716), as evidenced by Schumacher '767 (US 6,506,767).

Villani et al. disclose a method for preparing 8-Chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine (desloratadine or descarboxyloratine) as the acetic acid salt (Example III) as well as recrystallization of the free base from hexane (Examples V and VI).

Villani et al. do not disclose that the preparation of desloratadine produces a mixture of polymorph forms I and II. However, Schumacher '767 disclose that the preparation as described by Villani et al. results in a mixture of polymorphs. Therefore, Villani et al. inherently prepared a composition comprising a mixture of polymorphs forms I and II. Also, with regard to the physicochemical properties of the instantly claimed composition, these are inherent properties of a composition that would necessarily be present in the compositions of Villani et al. because the compositions of Villani et al. are within the scope of the compositions of the instant claims.

The examiner respectfully points out the following from MPEP 2112: "The discovery of a previously unappreciated property of a prior art composition, or of a



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scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that "just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel."

Also, regarding the claimed ratio of about 25 to about 75% of either form to the other, the Office does not have the facilities for examining the product of the prior art in order to establish that the product of the prior art does not possess the same weight to weight ratio of the claimed product. The examiner has provided sufficient evidence to indicate that the preparation by Villani et al. results in a mixture of desloratadine polymorph forms I and II that would fall within the instantly claimed ratio. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

With regard to the compositions prepared in instant claims 37-59, even though product-by-process claims are limited by and defined by the process, determination of

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patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. Therefore, Villani et al. anticipate the product as instantly claimed.

### ***Response to Arguments***

Applicant's arguments filed 29 September 2008 have been fully considered but they are not persuasive. Applicants argue on page 13 that the Office has failed to establish with any degree of certainty that the mixture so obtained by Villani et al. would inevitably contain the presently claimed specific ratio(s) of Form I and Form II.

The examiner respectfully argues that, in view of Schumacher '767, the recrystallized composition of Villani et al. is inherently a mixture of polymorph forms I and II. As noted above, the Office does not have the facilities for examining the product of the prior art in order to establish that the product of the prior art does not possess the same weight to weight ratio of the claimed product. The examiner has provided sufficient evidence to indicate that the preparation by Villani et al. results in a mixture of desloratadine polymorph forms I and II that would fall within the instantly claimed ratio. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences.

***New Grounds of Rejections***

1. Claims 1-13, 15-26, 28-59 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Schumacher '855 (EP 0 208 855), as evidenced by Schumacher '767 (US 6,506,767).

Schumacher '855 disclose a method for preparing 8-Chloro-6,11-dihydro-11-(4-piperidylidene)-5H-benzo[5,6]cyclohepta[1,2-b]pyridine (desloratadine or descarboxyloratine) as the acetic acid salt (pg. 26, Example III) as well as recrystallization of the free base from hexane (pg. 29-30, Examples V and VI).

Schumacher '855 do not disclose that the preparation of desloratadine produces a mixture of polymorph forms I and II. However, Schumacher '767 disclose that the preparation as described by Villani et al., which is the same as that disclosed by Schumacher '855, results in a mixture of polymorphs. Therefore, Schumacher '855 inherently prepared a composition comprising a mixture of polymorphs forms I and II. Also, with regard to the physicochemical properties of the instantly claimed composition, these are inherent properties of a composition that would necessarily be present in the compositions of Schumacher '855 because the compositions of Schumacher '855 are within the scope of the compositions of the instant claims.

The examiner respectfully points out the following from MPEP 2112: "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function

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or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that “just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel.”

Also, regarding the claimed ratio of about 25 to about 75% of either form to the other, the Office does not have the facilities for examining the product of the prior art in order to establish that the product of the prior art does not possess the same weight to weight ratio of the claimed product. The examiner has provided sufficient evidence to indicate that the preparation by Schumacher '855 results in a mixture of desloratadine polymorph forms I and II that would fall within the instantly claimed ratio. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. See *Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

With regard to the compositions prepared in instant claims 37-59, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even

though the prior product was made by a different process. See MPEP 2113. Therefore, Schumacher '855 anticipate the product as instantly claimed.

2. Claims 1, 4-13, 15-26, 28-59 and 61 are rejected under 35 U.S.C. 102(b) as being anticipated by Piwinski et al. (WO 92/00293) as evidenced by the arguments filed by Quimica Sintetica, S.A. in the Notice of Opposition to European Patent 1 507 531, and further evidenced by the Excerpt from the Opposition proceedings concerning EP 0 993 455 (all documents submitted in the IDS filed 01 October 2008).

Piwinski et al. disclose the preparation of desloratadine from loratadine by treating loratadine with KOH in an ethanol/water mixture at reflux temperature; wherein the desloratadine is extracted with ethyl acetate and dried to give a solid product, and the recovered solid is recrystallized from toluene (pg. 78, Example 1G).

Piwinski et al. do not disclose that the preparation of desloratadine produces a mixture of polymorph forms I and II. However, the Quimica Sintetica state that the preparation as described by Piwinski et al. in Example 1G inherently results in a mixture of polymorph forms I and II (pg. 13, ln. 1-5 and the Table). Also, the Excerpt from the Opposition proceedings concerning EP 0 993 455 provides experimental data showing that recrystallization of desloratadine from toluene results in a mixture of form I to form II of about 20:80, regardless of the starting materials ratio (pg. 7, last two paragraphs). Therefore, in the absence of evidence to the contrary, Piwinski et al. inherently prepared a composition comprising a mixture of polymorphs forms I and II. Also, with regard to the physicochemical properties of the instantly claimed composition, these are inherent

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properties of a composition that would necessarily be present in the compositions of Piwinski et al. because the compositions of Piwinski et al. are within the scope of the compositions of the instant claims.

The examiner respectfully points out the following from MPEP 2112: “The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art’s functioning, does not render the old composition patentably new to the discoverer.” *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In *In re Crish*, 393 F.3d 1253, 1258, 73 USPQ2d 1364, 1368 (Fed. Cir. 2004), the court stated that “just as the discovery of properties of a known material does not make it novel, the identification and characterization of a prior art material also does not make it novel.”

With regard to the compositions prepared in instant claims 37-59, even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. See MPEP 2113. Therefore, Piwinski et al. anticipate the product as instantly claimed.

### ***Conclusion***

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 01 October 2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is (571)272-9924. The examiner can normally be reached on 9:00 AM to 5:30 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/  
Primary Examiner, Art Unit 1616